REMARKS/ARGUMENTS

1. Applicants acknowledge with appreciation the courtesy of a telephonic interview on March 27, 2006 between Examiner David Sorkin and Applicants' Attorney Jeffrey Klayman to discuss the Office action of February 28, 2006.

The parties discussed the Examiner's position that Applicant did not clearly describe the type of solution and how to determine the useful lifetime of the solution, and therefore did not enable "predetermined useful lifetime."

Applicants' Attorney explained that the claim is enabled because the claims do not require "determining the useful lifetime" and that the specification clearly discloses that the working solution has a useful lifetime and discloses how the useful lifetime is employed in the process. Applicants' Attorney further explained that, based on the clearly stated understanding that the working solution has a limited useful lifetime, someone of ordinary skill would be able to make and use the claimed invention involving "determining whether mixing ... can be completed within a predetermined useful lifetime of the first solution and mixing ... only if mixing ... can be completed within the predetermined useful lifetime of the first solution."

No agreement was reached.

2. The Examiner has rejected claims 9-12 and 35-58 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The burden of proving lack of enablement is on the Examiner. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). MPEP 2164.04

makes it clear that the Examiner must identify the factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required. MPEP 2164.04.

Applicants respectfully submit that the claims are fully enabled. The application certainly provides sufficient disclosure to teach a person of ordinary skill in the art how to make and use the invention without undue experimentation. The application explicitly states that the working solution has a limited useable lifetime and that blood processing is coordinated to occur within the useable lifetime of the working solution (see page 11, lines 4-6). It is also clear that the process controller maintains various timers and keeps track of the age of working solution, and prevents blood processing operations if the working solution becomes too old (see page 18, lines 3-13). It is also clear that a determination is made as to whether there is a sufficient amount of time for performing the blood processing operation before the working solution expires

and that blood processing is prevented if it cannot be completed in time (see page 26, lines 25-29 and page 28, lines 24-26). Thus, it would have been clear to a person of ordinary skill in the art, for example, to implement a timer to monitor the useful lifetime of the working solution and to allow the secondary mixing to begin only if the mixing can be completed within the remaining useful lifetime of the first solution. To the extent the subject patent application is missing information about how to determine the useful lifetime of the working solution, a person of ordinary skill the art could certainly determine the useful lifetime without undue experimentation (in actuality, the useful lifetime is likely reported by the manufacturer). Furthermore, the Examiner has failed to supply specific technical reasons why one skilled in the art could not supply the missing information without undue experimentation, and therefore has not made a prima facie case of non-enablement.

Thus, Applicants reiterate that the claims are fully enabled. Furthermore, Applicants reiterate (from Applicants' last office action response), that none of the cited references teach or otherwise suggest the claimed invention. The claims are therefore both enabled and allowable.

Applicants note that at least one claim has been twice rejected and that, therefore, the application is ripe for appeal.

3. All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicant respectfully requests early allowance of the application. The Applicant requests that the Examiner contact the undersigned, Jeffrey T. Klayman, if it will assist further examination of this application.

4. The applicants do not believe any extension of time is required for timely consideration of this response. In the event that an extension has been overlooked, this conditional petition of extension is hereby submitted, and Applicants request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application.

Date: April 27, 2006

Respectfully submitted,

Jeffrey T. Klayman
Registration No. 39,250
Attorney for Applicants

Bromberg & Sunstein LLP
125 Summer Street
Boston, Massachusetts 02110-1618
Tel: (617) 443-9292
Fax: (617) 443-0004

01062/00D72 489953.1